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Fieldwork Summary Report

The LEGACY Girls Hormone Pilot Study:
Implications for Breast Cancer Prevention through Exploring
Hormone Biomarkers in Young Girls

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Abstract

To fulfill the Master of Public Health degree requirements from the University of San Francisco, I have inserted myself in the role of an intern at the Cancer Prevention Institute of California (CPIC). There, I completed 300 fieldwork hours on a research study called the LEGACY Girls Hormone Pilot Study. This pilot study seeks to gather preliminary data on urinary hormones steroids in developing girls and assess the feasibility of multiple urine samplings across menstrual cycles. Results will assist in planning a future prospective study in a large cohort of girls and to support a R01 grant seeking to address questions related to ovarian hormone during pubertal development and breast cancer risk. This fieldwork summary will include background on breast cancer risk factors including literature on hormones and risks factors of breast cancer, a description of the agency, an overview of the pilot study, and implications for breast cancer prevention. This paper will also provide evidence on how my fieldwork had contributed to my successful fulfillment of the MPH program competencies, core knowledge areas, and cross-cutting interdisciplinary competencies of public health. Overall, this invaluable experience have deepened my appreciation for the field of epidemiology as it relates to cancer prevention research and enhanced my understanding on the inner workings of a research study.

Keywords: Cancer prevention, breast cancer, hormones, public health, research, developing girls, risk assessments

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Introduction

In 2014, an estimated 232,670 new cases of invasive breast cancer will be diagnosed in the United States with 40,000 resulting in death (American Cancer Society, 2014). Breast cancer is the leading cause of death in women between the ages of 20 and 59 and the most common risk factors are being female and aging (Komen, 2014; Siegel et al., 2014). The Center for Disease Control and Prevention (CDC) reported that although the mortality rate of breast cancer has decreased drastically over the years due to advancement in treatment, early intervention efforts such as screening, health education, and research, breast cancer incidence rate have remained relatively stagnant (Edwards et al., 2013). Research on breast cancer generally seeks to enhance our understanding of the causes or etiology, treatment, and prevention of the disease. Although extensive studies on breast cancer have been employed over the years, the causes of breast cancer are still not fully understood which hampers our ability to prevent it.

Most studies on breast cancer primarily focus on adult populations studying women who have already developed breast cancer. In recent years, more progressive studies have increasingly sought to examine risks factors in younger populations by exploring measures of growth and development in children and adolescence and assessing risks factors associated with breast cancer (i.e. Wolff, et al., 2010; Bodicoat, et al., 2014; Biro, et al., 2013). In a report by Dr. Sandra Steingraber for the Breast Cancer Fund, a non-profit organization dedicated to breast cancer prevention, she indicates that there is an alarming trend of early pubertal development in girls in the United States (Steingraber, 2007). More startling is that early puberty in girls is

associated with a number of health problems in girls that persist later on in life. Early onset of menarche, for example, is now a well-established risk factor for breast cancer (Apter & Vikho, 1983; Kelsey, Gammon, & John, 1993; Collaborate Group on Hormonal Factors in Breast Cancer, 2012). Furthermore, retrospective studies on breast cancer patients have also supported findings on the adverse effects of early puberty. High levels of estrogen estradiol in the blood have been linked to increased breast cancer risk, almost doubled, in postmenopausal women (Key et al., 2002). Estrogen is a hormone highly crucial for sexual differentiation during prenatal development and a primary female sex hormone secreted from the ovaries (Chakraborty et al., 2012). Early menarche is associated with an increase lifetime exposure to estrogen thereby setting the stage for girls earlier on in their lives to heightened risks of breast cancer (Rosenfield, Cooke, & Radovick, 2008).

This relationship between hormones and breast cancer has been established primarily through research conducted on women. Few studies have attempted to compare hormone levels in girls with and without a family history of breast cancer. The lack of available data on hormones in developing girls is a huge oversight. Biro and colleagues (2013) inserted that puberty is an important developmental window of vulnerability when rapid growth takes place, including expansion and differentiation of breast stem cells. Thus, they propose that during preadolescence and adolescence is an ideal opportunity to assess susceptibility and risk for breast cancer. The LEGACY Girls Hormone Pilot Study, a study from researchers at the Cancer Prevention Institute of California, seeks to fill this gap in literature by gathering preliminary data on urinary hormones steroids in developing girls and testing the feasibility of collecting multiple urine samplings across menstrual cycles.

Background

In order to better understand the significance of studying hormone concentrations in developing girls, the following section will present a review of literature on factors associated with breast cancer risks during growth and development including age of menstruation and key hormone biomarkers. Furthermore, it will explore the feasibility of a new urine collection tool on collecting multiple samples in this specific population, preadolescent and adolescent girls.

Literature Review

Pubertal Development and Risk of Breast Cancer

Age of Menstruation. Advanced age, family history of cancer in a first-degree relative, personal history of *BRCA1/BRCA2* mutation, and lifestyle factors including adult weight gain, sedentary lifestyle, alcohol consumption are known risk factors for breast cancer in women (Stopeck et al., 2014). Early menarche is known to increase women's risk of developing breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer, 2012). Precocious puberty, which occurs when the pubertal changes occur earlier than expected, when menarche occurs before 8-9 years of age, also poses various risks. Precocious puberty can also lead to early diagnosis of breast cancer and obesity in adults (Biro, 2003). In a cohort of 104,931, there was 20% increase risk for women who experience breast development before or at age 10; height, age at menarche, and timing between breast development and menarche each independently were associated with a 20-30% increase in breast cancer risk (Bodicoat et al., 2014). Importantly, the study confirmed that time between developmental events is critically important to consider separately from the age of attainment (Bodicoat et al., 2014). Changes in pubertal timing can cause several physical and physiological diseases.

Height, Body Mass Index, and Birth Weight. In addition to early menarche, high birth weight, tall childhood stature, and large gains in childhood height and weight have also been

associated with increased breast cancer risk (Ahlgren et al., 2004; De Stavola et al., 2004). A positive correlation between body mass index and onset of puberty is believed to contribute to the trend and to some of the racial/ethnic differences. Girls with a higher body mass index typically exhibit earlier onset of puberty. It has been observed that many African-American girls have a higher body mass index than Caucasian girls, which can contribute to racial/ethnic differences in puberty (Roy et al., 2009). Roy and colleagues (2009) also found that higher birth weight correlated with earlier onset of puberty. The biologic mechanisms underlying associations with these indices of growth and development have not been established. These measures may be markers of hormones and growth factors that also determine breast ductal growth and differentiation, thereby setting the stage for future breast risk.

The Role of Hormones

Estrogen, Estradiol Level, and Breast Development. Breast cancer is a hormone responsive disease in part because breast tissue development and differentiation involves several hormones. Steroid hormones are produced in the ovary around the time of menarche and declines rapidly at around the time of menopause. Estrogen is a hormone secreted from the ovary that plays a vital role breast development in girls during puberty and is also involved in the timing of the growth spurt in pubertal girls (Chakraborty et al., 2012). In childhood, levels of estrogen estradiol are relatively low but again increase rapidly in the year prior to menarche (Rosenfield, Cooke, & Radovick, 2008). Breast growth during puberty is also stimulated by increasing estradiol along with insulin-like growth factor 1 (IGF-1) stimulated by growth hormone (GH) in the breast tissue. Understanding the effects of variations in the levels of concentration on breast tissue development and screening for elevated levels of specific hormones can be instrumental in not only contributing

to more knowledge about hormone but also targeting early prevention and interventions in at-risk groups, those with high concentration of estrogen earlier on in life.

Ovarian Steroid Hormone Exposures. Known risk factors for breast cancer includes ovarian steroid hormone exposure, yet the associations between ovarian hormones such as estradiol, progesterone remain unclear (Iversen et al., 2011). Emerging evidence has implicated progesterone in the relationship with breast cancer. In addition to estrogen estradiol secretion in the body during pubertal development, progesterone is also highly involved in differentiating breast tissue by influencing whether cell proliferate and guard against carcinogenic transformation (Lange & Yee, 2008). Few studies have examined the action of progesterone and breast cancer. In addition, serum estrogen concentration have been found to be viable clinical marker of exposure to estrogen and can be useful tools for assessing a woman's risk of breast cancer (Clemons et al., 2009). In conjunction with assessing currently known risk factors such as family history of breast and age of menarche, we can provide more accurate assessment of risk in individual women through measuring hormone concentrations.

Urine Collection. Given that the secretion of the ovarian steroid metabolites in the urine parallels serum concentrations of the parent hormones, estradiol, and progesterone (De Souza et al., 2010), collection of urinary samples serves as a reliable and feasible method of assessing ovarian steroids. Findings, however, from studies that do examine hormones have generally been inconsistent and based mostly on single samples, making them difficult to interpret (Boffard et al., 1981). In order to measure endogenous hormone levels in premenopausal women, some studies have opted for a well-established protocol involving measuring creatinine-adjusted urinary estrone glucuronide (E1G) and pregnanediol glucuronide (PG) levels in serial early morning urine samples on prespecified days of the menstrual cycle (Walker, et al., 2009). This

method was shown to be reliable in several studies. Although ideally, one would want to collect daily urine samples to assess variation in ovarian hormone concentrations, such frequent urine collection is not feasible in a large-scale study of young girls. Frequent serum sampling is not feasible, particularly in young girls (Santoro et al., 2003; Kesner et al., 1992). However, based on an analysis of daily urine samples collected by Dr. De Souza from a sample of young adult women, it appears that two urine samples per week (Mondays and Thursdays) may be sufficient to capture variation in hormones over the course of a menstrual cycle. The LEGACY Girls Hormone Pilot Study seeks to study the feasibility of applying a similar protocol. With few studies currently available on hormone data from urine samples collected over one or more menstrual cycles and many looking at small sample sizes, this pilot will fill the void by gathering data to support the planning of a future longitudinal study collecting multiple samples over more than one menstrual cycles in a large subset of girls.

In the present study, participating girls between the ages of 9 to 13 are asked to collect multiple first morning urine samples. Post-menarcheal girls, following the first menstrual cycle, are asked to collect urine three times a week (Mondays, Wednesdays, and Fridays) while pre-menarche girls are asked to collect one sample a month for 6 months. Due to large number of urine samples, a smaller midstream urine collection tool consisting of an absorbent sponge stripe and a slimmer plastic container called a “whizpop” was provided. The “whizpop” was originally developed by researchers at Penn State University to handle studies requiring multiple urine collections. First morning void were to be collected daily using “whizpops” and urine samples were kept frozen by subjects in their home freezers. In the present study, we tested the “whizpops’ ease of use, storage compatibility, and ability to measure and capture data on urinary

hormone steroids. Figure 1 below shows an image of the “whizpop” and highlights the size difference between a “whizpop” (left) and a standard 100ml urine container.



Figure 1. Whizpop vs. standard urine container.

In the next section, a description of the agency will be presented preceded by an overview of the pilot study along with its specific aims and project implementation.

Description of the Agency/ Project

Cancer Prevention Institute of California (CPIC) is a non-profit organization “dedicated to preventing cancer and to reducing its burden where it cannot yet be prevented” (CPIC.org). CPIC consists of a team of eighteen scientist conducting research to enhance our understanding of the causes of cancer, ways to prevent it or detect it early, and to improve outcomes for cancer survivor. The organization also participates in cancer surveillance activities through operating the Greater Bay Area Cancer Registry. Cancer diagnosis data collected from the nine Bay Area counties contribute to cancer statistics on cancer survival and outcomes and helps to guide the research conducted at the organization. In addition of the epidemiological research studies and surveillance efforts, CPIC is also involved in community development. The Community

Education program at CPIC provides resources, including information on workshops and recent publications, to cancer patients, their family, and leaders in the medical community.

The LEGACY Girls Study. Operating within the Research Department at CPIC is the LEGACY (Lessons in Epidemiology and Genetics of Adult Cancer from Youth) Girls Study. The LEGACY Girls Study multisite study funded by the National Cancer Institute to study girls aged 6 to 13 years old and how behavioral, environmental, and dietary factors influence pubertal growth and breast cancer risks. This prospective case-control cohort study follows 1040 girls from diverse racial and ethnic background and their parent or guardian for five years, with follow-ups every 6 months involving components including measurement of height, weight, and body composition, a collection of a first morning urine, Tanner staging, and data related to growth and development, dietary intake, and lifestyle factors. Approximately half of the girls come from families with a history of breast cancer and/or a known genetic mutation related to breast cancer risk and half without. The study seeks to gain a better understanding on the relationship between early behavioral/lifestyle factors, growth and development, and breast cancer risk.

The LEGACY Girls Hormone Pilot Study. In 2012, a pilot study by the Cancer Prevention Institute of California (CPIC) utilized participants from the LEGACY Girls Study to study ovarian steroid hormones and other phenotypes related to breast cancer risk (Keegan, 2010). The pilot study hypothesized that measures of growth and development are associated with hormones that influences breast ductal growth and differentiation, thereby setting the stage for future breast cancer risk. The small pilot study generated preliminary data and hormone assays from 15 post-menarcheal girls. Girls were asked to collect urine samples for 1 menstrual cycle and complete a menstrual calendar for 3 months. The present DCRA: LEGACY Girls

Hormone Pilot Study expands on the 2012 pilot study changing the urine collection protocol for girls from collecting urine samples for 1 menstrual cycle for post-menarche girls to 2 cycles and collecting 6-months of urine samples for pre-menarche girls instead of 3. Specific details of the LEGACY Hormone Pilot Study are described in the following section.

Implementation of Project

Researchers from CPIC now propose to build upon the current infrastructure of the LEGACY Girls Study and incorporate the collection of additional urine samples from post-menarcheal girls to better understand hormone biomarkers including estrogen and progesterone metabolites estrone-1-glucuronide (E1G) and pregnanediol-3-glucuronide (PdG), over the menstrual cycle. Three investigators, Dr. Esther John and Dr. Theresa Keegan at CPIC, and Dr. Whittemore at Stanford are involved in assessing the feasibility of the additional protocol component. A Developmental Cancer Research Award (DCRA) was granted to California LEGACY site to address the following aims:

1. Enroll 20 girls who are post-menarche and collect urine samples to assess:
 - a. Whether 3 urinary samples per week are sufficient to characterize ovarian hormone exposure over a menstrual cycle;
 - b. Whether girls are willing to collect samples for 2 cycles.
2. Enroll 20 pre-menarcheal girls aged 10-13 years and collect one urine sample per month for a period of 6 months to assess whether young girls are willing to collect urine samples according to this protocol.
3. Measure urinary estrone-1-glucuronide (E1G) and pregnanediol-3-glucuronide (PdG) concentrations in order to:

- a. Characterize and quantify ovarian steroid exposure, and cycle status in recent post-menarcheal girls;
- b. Demonstrate the feasibility of measuring low concentrations of ovarian steroids in pre-menarcheal girls and characterize variation and changes of E1G during the pubertal transition period; and
- c. Explore differences in exposure to urinary ovarian steroids by race/ethnicity, familial BC risk and measures of growth within developmental stage.

Tracking and Feasibility Analysis. Tracking the study components is highly essential to the planning of the R01 study and will help to improve the quality of the study design. In order to assess the feasibility of the protocol, we tracked the participation rates, adherence to the weekly collections of 3 samples for 2 menstrual cycles for post-menarche girls, and adherence to 1 monthly sample over a 6-month period for pre-menarche girls, willingness to store samples in the home freezer, completion rates of specific questionnaire items, and completeness of menstrual calendar are carefully monitored. A field interviewer sends weekly correspondence through email and texts to daughters to remind them of the collection date and update the urine collection status. These updates are noted in an ACCESS database, which also tracks the status of the questionnaires. CPIC is an organization that highly values the privacy and confidentiality of study participants. Consent and assent forms are IRB approved and must be signed by the participants. Each participant and their mothers have a unique and non-identifying ID, which can be used to access their online questionnaires via Qualtrics, online data collection software.

Results

Although the pilot study is still in the data collection phase and results are not available yet for the urinary analysis and questionnaire responses, I can still speak to the feasibility of the study and basic demographic variables.

Demographic Variables

The average age of the girls was 11.1 years. 40% of the girls self-identified as non-Hispanic White, 17% as Asian-American or Asian, 17% as Hispanic or Latina, and 33% mixed-race. In the post-menarche group, the average menarche age was 11.75 years.

Feasibility Measures and Findings

The study design for the LEGACY Girls Hormone Pilot Study is simple and was drawn from successful studies in the past. It mirrors the existing LEGACY Girls Study in effectively tracking the components through an ACCESS database system and utilizes Qualtrics as a platform to collect questionnaire data. This makes the study sustainable and feasible since it is using already established measures that have been shown to be effective.

The recruitment goal for the study was 40 girls, 20 girls of pre-menarche status (girls who have never had a period) and 20 girls of post-menarche status (girls who have started their periods). Pre- and post-menarche status was established through self-reported responses in an initial screening call. Initial recruitment efforts yielded 37 girls along with their parent/guardian who agreed to participate in the study, which equates to a 92.5% recruitment rate. Of which, 22 (59.5%) were pre-menarche and 15 (40.5%) were post-menarche status. As the study progressed, 7 girls (18.9%) decided to no longer participate. As of August 2014, 81.8% (18 out of 22) of the pre-menarche girls and 80% (12 of the 15) of post-menarche girls are still actively participating. Of these 30 remaining girls, 18 (60%) are pre-menarche and 12 (40%) are post-menarche.

Based on responses compiled from the exit interview questionnaires completed by 13 participants and their parent/guardian, we assessed the comprehension of calendar instructions,

ease of use of the whizpops. All 13 girls (100%) found the instructions easy to understand and the whizpops easy to use. 92.3% of mom also reported that they did not have issues with storage. One mom did indicate that she had 2 daughters participating so space was an issue. Responses show that the study protocol and materials are appropriate for the age range and is promising in using for replication in future studies.

Public Health Significance

A better understanding of early-life ovarian steroid exposure and their relationship to growth and development indices that are associated with breast cancer risk will help us improve our ability to develop and evaluate new breast cancer prevention strategies at a younger age. For example, an intervention study to reduce dietary fat intake in girls aged 8-10 years found a reduction in serum estradiol and other hormone measures during the follicular phase of the menstrual cycle at the year 5-post study visit (Dorgan, Hunsberger, & McMahon, 2008). Although follow-up at ages 25-29 years no longer found evidence of lower serum estradiol levels in the intervention group (Dorgan et al., 2010). This study nevertheless demonstrates that adolescent ovarian steroid levels are modifiable by lifestyle factors during a key period of breast development. The current LEGACY Girls Hormone Pilot Study further builds on our knowledge of ovarian steroid hormones in addition to highlighting potential differences between pre-menarche girls and post-menarche girls. By studying the feasibility of such studies, we could also expand on the research done on this population. Effective risk assessment tools such as the use of whizpop in vulnerable populations can help public health practitioners effectively target interventions to yield the greatest impact.

MPH Competencies Addressed

With my interest in cancer prevention and research, my preceptor and I developed six goals to be completed throughout the fieldwork experience. Those included: (1) developing public health research skills and assisting in the implementation of a pilot study, (2) gaining comprehensive understanding of existing literature on the effects of hormones, menstruation, and growth and development on breast cancer risks in girls, (3) assisting in the enhancement of study protocol for the LEGACY Girls Hormone Study, (4) assisting in modifying materials used to perform components of the LEGACY Girls Study, (5) attending professional development and research seminars and trainings, and (6) developing basic knowledge of SAS software program (language, simple analysis, codes). By carrying out the learning objectives for each of these goals, I was able to fulfill the MPH program competencies, four core competencies of public health, and four cross-cutting/interdisciplinary competencies.

For the purpose of my fieldwork, I performed preliminary literature review on the risk of breast cancer in developing adolescent girls. I examined potential differences in risk by demographic and socioeconomic variables such as race, ethnicity, age, and income as well as risk factors such as genetic pre-disposition and family history and environmental exposures. This fulfills the first MPH competency, which is the ability to assess, monitor, and review the health status of populations and their related determinants of the health and illness. The second competency is to demonstrate the ability to utilize the proper statistical and epidemiologic tools to assess community needs and program outcomes. My duties for this internship included assisting in tracking completion of online questionnaires completed by participants through a developed ACCESS database. This data is later pulled and analyzed by Epidemiologist to assess variables such as age as well as completion of study components. I also had the opportunity to shadow an epidemiologist who compiles data for the LEGACY Girls Study and develop a brief

understanding of statistical tools for assessment. For my personal and professional growth in statistical programming, I completed a SAS online training course that demonstrates my understanding of essentials of statistical analysis and tools.

The third MPH competency is the ability to identify and prioritize the key dimensions of a public health problem by critically assessing public health literature utilizing both quantitative and qualitative sources. As noted earlier, I was able to conduct a thorough and comprehensive review of literature, which also demonstrates my competency in utilizing online journal databases to gather various types of data. I am competent in comprehending measures of risk such incidence rates and prevalence rate made available by the CDC and other health organizations. Furthermore, my fieldwork experience was especially instrumental in allowing me to understand methods for assessing, preventing, and controlling environmental hazards that pose risks to human health and safety. This study is testing the feasibility and improving how epidemiological research is done on girls, an understudied group. Researchers assessing the use of a more appropriate urine collection tool, a “whizpops”, along with its ability to quantify hormonal factors associated with increased risk later in life. As apart of my feasibility report, I also helped to evaluate best practices and research methods on working with adolescent populations in research studies. Findings from this study will help guide interventions or prevention strategies in communities that are of greater risks or are disadvantaged. These tools allow public health practitioners to better target their audience and make the greatest impacts in the most vulnerable communities.

Another goal of my fieldwork was to assist in the improvement of the pilot study protocol. Thus, I suggested the incorporation of an exit interviewer survey component that will be administered at the end of the study. The Program Manager and my preceptor were receptive

of the idea and we moved forward with it. I created the questionnaire which aims to evaluate how well the study materials were communicated, whether there were issues with urine collection, storage compatibility, and whether the families would be interested in further participation (See Appendix B.). The responses from the questionnaire will be utilized to improve future planning of the study protocol and design for the larger study. I believe this demonstrates my ability to articulate the relationship between healthcare delivery, more specifically health research delivery and the targeted population. This will also promote sound financing (feasibility) because it ensures that there is enough interest in the study for it to be viable and the organization is not wastefully allocating funds towards a study with no public interest.

Another role I took on as an intern was tracking and providing weekly summary report of the participating subjects. I was able to apply program planning, management, and evaluation skills in doing so. It also allowed me to demonstrate my leadership abilities as a coordinator for the project. My preceptor allowed me to be independent and was highly supportive in giving me the appropriate level of work including the ability to oversee a field staff and help in coordinating the home visits and collecting study components. In addition, I attended monthly meetings between the coordinator and researchers and I was not hesitant to offer my ideas and suggestions to improve the study protocol. I also took some time to review the IRB approved consent forms for moms and assent forms for daughters ensuring that they are aware of potential risks. It is important in public health not only to obtain data but also protecting the safety of participants in the studies. Therefore, for the LEGACY Girls Hormone Pilot Study, I ensured that the consent and assent forms were collected prior to participation to the study. In the

feasibility report, I also made suggestions to the hormone pilot study protocol to address potential cultural barriers to participating in the study and to help enhance the quality of the data.

With the approval of my preceptor, I also participated in the Minority Training Program in Cancer Control Research (MTPCCR) program as part of a professional and leadership development goal in my learning contract. This program aims to increase understanding of the power of research to effect change, promote awareness of the strengths and limitations of research methods, theory, and interventions in eliminating health disparities, and develop participant's interest in cancer control research, from surveillance to epidemiology, individual behavior change, health services, and policy research. This enriching program gave me the opportunity to network with current researchers from various fields. I developed a greater understanding of the interdisciplinary nature of public health and how collaborating with different experts in the field can be beneficial in conducting innovative and applicable research studies. This training also touches on cross-cutting competencies of public health tied to diversity and culture. MTPCCR believes in the concept of being an "insider" researcher, which sees our culture as our strength. Because we identify with that population or group, we are more aware of the barriers and issues and thus can better cater our research to eliminating health disparities particularly in minority and at-risk populations.

My fieldwork experience touched on four of the core knowledge areas: epidemiology, social and behavioral sciences, environmental health, and public health administration and leadership. As an intern of the LEGACY Hormone Pilot Study, I assisted in the tracking and performing quality control of collected data, which helps to better assess the risk of the population and factors affecting the population. These tasks relates to the field of epidemiology, which examine the causes of health problems and risk factors in the population. For social and

behavioral science, I conducted literature review of social and cultural factors present in the Hormone Pilot Study that consider differences in breast cancer risk and breast cancer risk factors by family history, age, ethnicity and race. Literature suggest that African American women are disadvantage due to their higher exposure to chemicals, higher mortality rates even though their overall incidence rate are lower than white women. It is also found that factors like quality of health care, later follow-ups after a mammogram, and their risks of developing more aggressive triple-negative breast cancer are reasons for their higher mortality rates. Assessing cultural barriers in this population as well as policies may improve their health outcome. In addition, through developing the exit interview questionnaire, it opens up the conversation between the researchers and participants on more effective ways to carry out the study and assess barriers they may face.

Along with epidemiology, environmental health is the next relevant core knowledge area addressed in my fieldwork. Harmful exposures to environmental hazards such as chemicals are risk factors for early menarche, which indirectly affects early exposure to hormones such as estrogen. Epidemiological studies like the LEGACY Girls Hormone Pilot Study is highly significant in guiding prevention strategies to decrease exposure to excess environmental hazards as high-level of estrogen in later life for women increases their chances of development breast cancer. It is now more inherent to me the value accessing hormone levels and promoting modification of diet and/or physical activity to reduce the level of exposure in at-risk groups.

Last, I believe my experience also contributed to my public health administration and leadership skills. Through examining the works of local groups such as a the Breast Cancer Fund and the Environmental Working Group, I have learned about ways researchers and individuals are combatting the environmental issues associated with breast cancer. This pilot study, though

small in scope, has the potential to inform best practices and methods to reach broader populations. I see the prospective of improving the quality of involvement from the community and how findings from the study can also inform the public about early prevention strategies. It can also inform policy to address issues of early hormone exposure caused by obesity, endocrine disrupting chemicals, and environmental stressors. More epidemiological longitudinal research must be done to elucidate the nature of early pubertal onsets including the associated hormones and breast cancer development later in life. Appendix A. shows the full Learning Contract with detailed descriptions of the goals and associated learning objectives can be found

The competencies listed above were completed with the knowledge acquired through my graduate education from USF and the MPH program. Biostatistics, epidemiology, environmental health, and Advanced Epidemiology with Statistical Software Application were especially relevant courses in preparing me to carry out my activities at my fieldwork.

Conclusion

From conducting the review of literature on this topic, I realized that breast cancer etiology is complex and there continues to be significant gaps in our knowledge on the development of this disease. These gaps in knowledge impede our ability to prevent breast cancer and reduce its high morbidity and mortality rates. The strongest risk factors we know for breast cancer so far are being female and having a family history of breast cancer. Whether the increased risk manifests early in life and whether alterations in steroid hormone levels may be one of these manifestations is still unknown. Studies like this one will not only shed light on early mechanisms in breast cancer etiology, but will also contribute to better understanding the potential of steroid hormones as risk markers and inform prevention efforts geared at reducing breast cancer risk.

Overall, the fieldwork was a great introduction for me into the field of epidemiology. It allowed me to actively take part in the implementation of a research study and allowed me to understand an issue that I had little prior knowledge about. I learned that in addition to acquiring an understanding on what the literature has to say about the issue, it is equally important to know how the studies are carrying it out. Understanding the methodology and protocol employed helps us to evaluate how valid and reliable the data really is and whether it is answering the intended research question. Personally, I feel like I've grown a lot through the experience, especially in my ability to be flexible and to think on my feet. It is especially important to have these skills with working on pilot studies, which are prone to changes along the way. My preceptor was helpful and open to allowing me to work independently. She was very receptive of my suggestions and allowed me to take initiative on key parts of the study. Through the experience, I was able to gain more confidence in my ability to contribute in public health especially in the realm of research. As a future public health practitioner, I am optimistic that more studies like the LEGACY Girls Hormone Pilot Study will continue to provide valuable information on ways to combat preventable diseases.

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Appendix A. Learning Contract



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Fieldwork Form: Student Preceptor Agreement

(To be completed by the student in consultation with the field experience preceptor.
Attach the Scope of Work and MPH Student Competency Inventory)

Student: Muoi (Jenny) T. Nguyen

Agency and Department/Division/Program: Cancer Prevention Institute of California
Research Department, LEGACY Girls Hormone Pilot Study

Field Supervisor: Maria C. Talosig-Garcia, MPH

Dates of Placement: 5/19/2014 – 8/30/2014

I. Scope of Work

Using the attached matrix to describe the project(s) in which you will be contributing, fill out following sections:

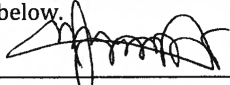
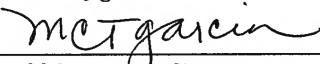
1. Overall goal(s) of internship
2. Measureable objectives that relate to the achievement of goal(s)
3. Activities that correspond to each objective
4. Start-end dates
5. Responsible parties involved
6. Tracking measures (evaluation indicators)

II. MPH Student Competency Inventory

Of the Public Health Competencies listed in the attached document; identify competency areas you wish to address through the fieldwork experience.

III. Acknowledgements

We have participated in development of this field-training proposal and agree to the conditions specified above. If it becomes necessary to alter any of the specified conditions, we agree to make the changes known to each of the persons whose signatures appear below.

 _____ Student Signature	5/16/14 _____ Date
 _____ Field Supervisor Signature	5/16/14 _____ Date
_____ MPH Practicum Coordinator	_____ Date



Masters in Public Health
Fieldwork Form: Student Preceptor Agreement

Supervised Field Training in Public Health
 Student Scope of Work

<i>Goal 1: To develop public health research skills and assist in the implementation of a pilot study.</i>				
Objectives (S)	Activities	Start/End Date	Who is Responsible	Tracking Measures
Understand the inner workings of a research study	Assist in the daily operations of the LEGACY Hormone Pilot Study. Duties include: <ul style="list-style-type: none"> • Prepping and sending out appropriate documents, consent forms, questionnaires, and enclosures to study participants • Coding Qualtrics surveys in the Access tracking system • Assisting Project Coordinator in quality control activities in the lab 	May 19 th – Aug 30 th (on-going)	Jenny Nguyen	-
Track progress of participants of the hormone pilot study	<ul style="list-style-type: none"> • Providing weekly reports of participants progress • Ensure that consent forms, assent forms, surveys, and biospecimen are collected • Provide office support for field staff and assist in communicating pending components 	May 19 th – Aug 30 th (on-going)	Jenny Nguyen	Intern will submit a summary report of all home visits/appointments every Friday.
Observe how field staff interacts with study participants	<ul style="list-style-type: none"> • Shadow field staff during 	TBD	Jenny Nguyen	Provide a summary of the visit. (i.e. Did the IP follow protocol?)



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	<ul style="list-style-type: none"> • a home visit • Observe dynamics between interviewer and participants and collect field notes 			Observations, etc.) *Due date subject to the date of the scheduled visit. Notes turned in within the week.
<i>Goal 2: To gain comprehensive understanding of existing literature on the effects of hormones, menstruation, and growth and development on breast cancer risks in girls.</i>				
Objectives (S)	Activities	Start/End Date	Who is Responsible	Tracking Measures
Develop understanding of the relationship between hormones, menstruation and other risks factors of breast cancer.	<ul style="list-style-type: none"> • Conduct a preliminary literature review on risks factors of breast cancer • Identify the population of interest • Determine gaps in literature and how present study addresses them 	May 19 th – May 26 th (1 week)	Jenny Nguyen	-
Cont.	<ul style="list-style-type: none"> • Research current literature on age, early menstruation, pubertal status and other factors that are linked to enhanced risk for breast cancer. 	May 27 th - June 4 th (1.5 weeks)	Jenny Nguyen	-
Develop understanding study design/methods, and collection tools.	<ul style="list-style-type: none"> • Read original grant proposal and understand the purpose of the pilot study • Examine the efficacy of "whizpop" to collect hormonal data • Explore the use of "whizpops" and alternative urine 	May 19 th – Aug 15 th (on-going)	Jenny Nguyen Enid Satariano, MPH (Program Manager) will assist in providing literature that helped develop the pilot study Maria Talosig-Garcia, MPH (Preceptor) may help guide and answer questions on the	Final literature review will be incorporated into the "Fieldwork Summary Report" Deadline – Aug 15 th



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	<ul style="list-style-type: none"> collection tools, menstruation calendars, and other components that may be compatible research design. Hypothesize how present study can be used to develop prevention programs or tools to decrease breast cancer in at-risks populations. 		project plan, design and methods used.	
Goal 3: To assist in the enhancement of study protocol for the LEGACY Girls Hormone Study.				
Objectives (S)	Activities	Start/End Date	Who is Responsible	Tracking Measures
Synthesize the issues experienced during the pilot study and provide strategies to enhance protocol.	<ul style="list-style-type: none"> Track potential issues that occur during the implementation. Provide a written report summarizing issues experienced and suggested improvements. Create an exit interview form to gather data on issues and suggestions by participants. Intern will compile the information from the survey and incorporate it in to the report. 	May 19 th – Aug 15 th (on-going)	Jenny Nguyen	Report will be submitted on Aug 15 th . Exit interview survey submitted June 11 th .
Goal 4: To assist in modifying materials used to perform components of the LEGACY Girls Study.				
Objectives (S)	Activities	Start/End Date	Who is Responsible	Tracking Measures
To modify the Optical Spectroscopy User Manual.	<ul style="list-style-type: none"> Read current user manual and physically highlight the relevant 	May 20 th – May 30 th	Jenny Nguyen	Draft will be submitted on May 30 th for further review by Enid and Maria.



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	<ul style="list-style-type: none"> points. Editing current version to summarize the protocol for operating the OS machine and the accompanying computer component, making the manual more user friendly for interviewers. 			
Professional Development/Training				
Goal 5: To attend professional development and research seminars and trainings.				
Develop:	Activities	Start/End Date	Who is Responsible	Certificate of Completion?
<ul style="list-style-type: none"> Understanding of the power of research to effect change Awareness of the strengths and limitations of research methods, theory, and interventions in eliminating health disparities Interest in cancer control research, from surveillance to epidemiology, individual behavior change, health services, and policy research Research, networking, information seeking skills, and motivation and ability to successfully apply to a doctoral program. 	<ul style="list-style-type: none"> Attend the Minority Training Program in Cancer Control Research 	June 7 th – June 11 th	Jenny Nguyen	
Statistical Software Skills				
Goal 6: To develop basic knowledge of SAS software program (language, simple analysis, codes).				



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Develop: <ul style="list-style-type: none"> Understanding of basic function of the SAS Program Knowledge of common commands used in SAS Skill to pull and create datasets from LEGACY data Knowledge of the various processes in SAS related to the LEGACY Girls Study. 	<ul style="list-style-type: none"> Shadow Meera Sangaramoorthy, MPH, an Epidemiologist at CPIC and how she completes data requests for the LEGACY Girls Study. Review SAS User Guides and language manuals provided by Meera. Watch online tutorials developed by SAS. Take the Free 'SAS Programming 1' e-course on website, 	July 1 st – August 15 th First shadowing session is July 1 st . Second session is mid-August.	Jenny Nguyen Meera Sangaramoorthy, MPH	<ul style="list-style-type: none"> Intern will show completion of the online training course.
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Master of Public Health Program

MPH PROGRAM COMPETENCY INVENTORY – Attachment 2 USF

MPH Competencies	Proposed Activities	Number of Hours (Estimated)
1. Assess, monitor, and review the health status of populations and their related determinants of health and illness.	Perform a literature review on the risk of breast cancer in a special population, adolescent girls. Examine possible differences by demographic and socioeconomic variables such as race, ethnicity, age, income as well as other risk factors such as genetic pre-disposition/family history and environmental exposure. Determine the possible gaps in literatures.	25
2. Demonstrate the ability to utilize the proper statistical and epidemiologic tools to assess community needs and program outcomes.	Compile statistics that confirms the need to address the population researched (ex. girls, genetics/family history, SES, growth and development factors).	15
3. Identify and prioritize the key dimensions of a public health problem by critically assessing public health literature utilizing both quantitative and qualitative sources.	Conduct a comprehensive review of literature on biomarkers such as hormones related to growth and development in adolescent girls that may be linked to risks of breast cancer later in life. Determine how hormone biomarker information collected from urine samples can provide insight on early-life factors that may influence health later in life.	30
4. Specify approaches for assessing, preventing, and controlling environmental hazards that pose risks to human health and safety.	Further examine existing literature on the use and/or proposed use of "whizpops" in study to assess the risk to younger participants. Evaluate best practices and research methods with working with adolescent populations in research studies.	10



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5. Apply theoretical constructs of social change, health behavior and social justice in planning community interventions.	Synthesize the issues experienced during the pilot study and provide strategies to enhance protocol.	20
6. Articulate the relationship between health care delivery and financing, public health systems, and public policy.	Shadow study interviewer on a home visit with the participant.	5
7. Apply evidence-based principles to the process of program planning, development, budgeting, management, and evaluation in public health organizations and initiatives.	Evaluate the feasibility of the pilot hormone study. Summarize findings that may contribute to the development of future grant proposals.	15
8. Demonstrate leadership abilities as collaborators and coordinators of evidence based public health projects.	*Attend meetings between coordinators, researchers, and epidemiologist.	8
9. Identify and apply ethical, moral, and legal principles in all aspects of public health practice.	Address legal and ethical concerns of the Pilot Hormone Study, including human-subjects protections, etc.	5
10. Develop public health programs and strategies responsive to the diverse cultural values and traditions of the communities being served.	Present a report on possible modification or suggestions to the hormone pilot study protocol to address barriers to participating in the study and to help enhance the quality of the data.	25
11. Effectively communicate public health messages to a variety of audiences from professionals to the general public.		
12. Advance the mission and core values of the University of San Francisco.		
CEPH Core Knowledge Areas	Proposed Activities	Number of Hours (Estimated)
Biostatistics		
Epidemiology	Assess the risk and compile statistics that confirms the need to address the	40



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	population researched (ex. girls, genetics/family history, SES, growth and development factors).	
Social and Behavioral Sciences	Address social and cultural factors present in the Hormone Pilot Study	50
Environmental Health		
Public Health Administration and Leadership	Develop best method of reaching populations in the Bay Area, in regard to study participation, quality of involvement, cost, etc.	25
Cross-Cutting/Interdisciplinary Values	Proposed Activities	Number of Hours (Estimated)
Communication and Informatics	Collect necessary information and provide suggestion for improvement for future grant proposal; attend meetings and report on the weekly progress of participants during the study	60
Diversity and Culture	Attend the MTPCCR Program: Helps to develop awareness of the strengths and limitations of research methods, theory, and interventions in eliminating health disparities particularly in minority and at-risk populations.	40
Leadership		
Professionalism	Attend the MTPCCR Program: Helps to develop research, networking, information seeking skills, and motivation and ability to successfully apply to a doctoral program.	40
Program Planning		
Public Health Biology		
Systems Thinking	Take into account various roles of LEGACY Girls Hormone Study staffs, researchers, coordinators, and community members to establish effective recruitment methods, implementation of protocol, and fulfill our research capacity	50

Appendix B. DCRA: Pre/Post Exit Interview Survey



LEGACY GIRLS Hormone Pilot Study: Exit Interview Form

Questions for participating girls:

1. Did you have any problems filling out the calendars? Yes _____! No _____!

Please explain:

2. Were the instructions easy to understand? Yes _____! No _____!

Please explain:

3. Did you miss any days? Yes _____! No _____!

4. Did you have any problems with completing the collection of the urine?

Yes _____! No _____!

5. Please answer the following questions: Circle Yes or No

Were the 'whizpops' easy to use?	Yes	No
Was the sample box easy to use?	Yes	No
Was it difficult to write the date and time on the whizpops?	Yes	No
Was storage of the samples in your freezer ok?	Yes	No
Was it difficult for you to collect 3 samples a week?	Yes	No

6. Would you be willing to participate in this study for another 2 years?

Yes _____! No _____!

POST - Revised 6.10.14



LEGACY GIRLS Hormone Pilot Study: Exit Interview Form

Questions for participating girls:

1. Did you have any problems filling out the calendars? Yes _____% No _____%

Please explain:

2. Were the instructions easy to understand? Yes _____% No _____%

Please explain:

3. Did you miss any days? Yes _____% No _____%

4. Did you have any problems with completing the collection of the urine?

Yes _____% No _____%

5. Please answer the following questions: Circle Yes or No

Were the 'whizpops' easy to use?	Yes	No
Was the storage box easy to use?	Yes	No
Was it difficult to write the date and time on the whizpops?	Yes	No
Was storage of the samples in your freezer ok?	Yes	No
Was it difficult for you to collect 1 sample, once a month?	Yes	No

6. Would you be willing to participate in this study for another 2 years?

Yes _____% No _____%

PRE - Revised 6.10.14

Questions for mothers of participating girls:

1. Did you have any issues storing the samples in your freezer?

Yes _____! No _____!

2. Would you be willing to participate in this study for another 2 years?

Yes _____! No _____!

If no, why?

3. Would you be comfortable with your daughter(s) providing other biospecimen such as blood or saliva samples? (Blood sample once a year and saliva samples every 6 months).

Yes _____! No _____!

If no, why?

4. Are you willing to travel to our office in Fremont for a visit once a year? Travel expenses will be covered.

Yes _____! No _____!

5. Please provide any additional feedbacks or comments below.

Thank you.

POST - Revised 6.10.14

Questions for mothers of participating girls:

1. Did you have any issues storing the samples in your freezer?

Yes _____% No _____%

2. Would you be willing to participate in this study for another 2 years?

Yes _____% No _____%

If no, why?

3. Would you be comfortable with your daughter(s) providing other biospecimen samples such as a saliva sample, once every 6 months?

If no, why?

4. Are you willing to travel to our office in Fremont for a visit once a year? Travel expenses will be covered.

Yes _____% No _____%

5. Please provide any additional feedbacks or comments below.

Thank you.

PRE - Revised 6.10.14